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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/554,956	07/11/00	BADLEY	R PM-270584

PILLSBURY MADISON & SUTRO
1100 NEW YORK AVENUE NW
NINTH FLOOR EAST TOWER
WASHINGTON DC 20005-3918

HM12/1030

EXAMINER

NELSON, B

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

10/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/554,956

Applicant(s)
Badley et al.

Examiner
Brett Nelson

Group Art Unit
1648



☒ Responsive to communication(s) filed on Jul. 11, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 17-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-16, drawn to a method of detecting the presence of an analyte of interest.

Group II, claims 17-19, drawn to an apparatus.

2. The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Schramm et al. (WO 91/05626) disclose a displacement assay which uses a signal generating member for detection and not SPR (abstract). Therefore, claim 1 lacks a special technical feature.

3. During a telephone conversation with Paul Kokulis on Oct. 26, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-19 are withdrawn

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from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

6. The specification is also objected to because it does not contain a Brief Description of the Figures.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.

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- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Objections

4. The claims are objected to because they lack a proper introduction. The present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). MPEP § 608.01(m).

Claim Rejections - 35 USC § 112

7. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear what is intended by the terminology "affinity-related manner". It is suggested that applicant spell out "SPR" in claim 1.

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Claim 4 is indefinite because it is unclear what applicant intends by the phrase "a portion which facilitates reversible immobilization."

The term "relatively loosely" in claim 7 is a relative term which renders the claim indefinite. The term "relatively loosely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation analogue, and the claim also recites mimetope which is the narrower statement of the range/limitation.

Claim 12 is indefinite because it is unclear what is intended by the phrase "electrochemical properties".

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Claim 16 recites an improper Markush group. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 706.03(Y). Clarification is required to overcome this rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 7-10 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262). The claims are drawn to a method of detecting the presence of an analyte in a sample comprising providing a first surface having a displaceably moiety reversibly immobilized, exposing the first surface to a sample wherein any analyte in the sample displaces the displaceable moiety causing the displace moiety to contact a second surface bearing a capture moiety, and detecting a signal. It should be noted that the claims recite "open" language and fail to exclude other reagents or steps. Schramm et al. discloses a process for detecting an analyte in sample comprising contacting a first surface, upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample

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displace the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal, which can be produced by fluorescence or enzymes. Schramm et al. also teach that the two surface can be on separate or the same supports and that planar, porous or particulate surfaces may be used (abstract, Figs. and pp. 3-5). The method of Schramm et al. is the same as the claimed method. Therefore, Schramm et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) in view of Tom-Moy et al. (EPA 0 416 730). The claims are drawn to a

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method of detecting the presence of an analytes as described above wherein the detectable signal comprises the generation or modulation of an evanescent or acoustic wave. The teachings of Schramm et al. are described above. Schramm et al. differ from the claimed invention by not specifically teaching detection by the generation or modulation of an evanescent or acoustic wave. Tom-Moy et al. disclose assays for detecting binding of ligands and teach that detecting modulation of acoustic waves reduces the user time required to customize the measurement surface to render it capable of binding selected compounds and allows for calculating the mass or concentration of an analyte (abstract and p. 3). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schramm et al. by employing detection by the generation or modulation of an evanescent or acoustic wave as taught by Tom-Moy et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use acoustic wave detection in order to reduce steps and reagents by elimination having to label the detectable moiety with a fluorescent, luminescence or radioactive tag. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because Tom-Moy et al. teach that detecting modulation of acoustic waves reduces the user time required to customize the measurement surface to render it capable of binding selected compounds and allows for calculating the mass or concentration of an analyte.

12. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garland et al. (WO 92/18867) in view of Tom-Moy et al. (EPA 0 416 730). The claims are drawn to a method

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of detecting the presence of an analytes as described above wherein the detectable signal comprises the generation or modulation of an evanescent or acoustic wave. Garland et al. disclose a process for detecting an analyte in sample comprising contacting a first surface, upon which a displaceable moiety such as an antibody, analyte or analogue has been reversibly bound, with a sample wherein analyte in the sample displace the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal via SPR. Garland et al. also teach that the two surface can be on separate or the same supports and that planar, porous or particulate surfaces may be used (abstract, Figs. and pp. 6-10). Garland et al. differ from the claimed invention by not specifically teaching detection by the generation or modulation of an evanescent or acoustic wave. Tom-Moy et al. disclose assays for detecting binding of ligands and teach that detecting modulation of acoustic waves reduces the user time required to customize the measurement surface to render it capable of binding selected compounds and allows for calculating the mass or concentration of an analyte (abstract and p. 3). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Garland et al. by employing detection by the generation or modulation of an evanescent or acoustic wave as taught by Tom-Moy et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use acoustic wave detection in order to reduce steps and reagents by elimination having to label the detectable moiety with a fluorescent, luminescence or radioactive tag. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable

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expectation of success in producing the claimed invention because Tom-Moy et al. teach that detecting modulation of acoustic waves reduces the user time required to customize the measurement surface to render it capable of binding selected compounds and allows for calculating the mass or concentration of an analyte.


13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner James C. Housel whose telephone number is (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn
October 26, 2000



BRETT L. NELSON
PATENT EXAMINER